

"Express Mail "Mailing Label Number EF 210 466 089 US
Date of Deposit December 14, 2001

I hereby certify that this paper or fee is being
Deposited with the United States Postal Service
"Express Mail Post Office To Addressee" service
under 37 CFR 1.10 on the date indicated above and
is addressed to the Assistant Commissioner for Patents,
Washington, D. C. 20231.

Lanette Burton

(Type or printed name of person mailing paper or fee)


(Signature of person mailing paper or fee)

A COMBINATION FOR MANAGING THE INVOLUNTARY LOSS OF BLADDER CONTROL

BACKGROUND OF THE INVENTION

Urinary incontinence is an involuntary leaking of urine, which can occur when any of the normal functions of the bladder are disrupted. There are three major categories of urinary incontinence, which are classified according to etiology: stress incontinence (SI), also referred to as genuine stress incontinence; detrusor instability (DI), also referred to as urge incontinence (UI); and overflow incontinence. In addition, many patients, especially women who have given birth to one or more children, and older women are diagnosed with mixed incontinence, such as a combination of stress incontinence and urge incontinence.

The primary etiological factor producing SI is the incomplete transmission of abdominal pressure to the proximal urethra due to displacement from its intra-abdominal position. SI is classified as a failure to store urine. In this type of urinary dysfunction, leakage occurs during times of abdominal pressure or "stress" such as coughing, sneezing, laughing, bending or lifting heavy objects. The frequency and severity of such urine loss can increase as the muscles and tissues, particularly those near the urethro-vaginal myofascial area, grow weaker. It has also been recognized that the urinary sphincter muscle, which is located at the upper end of the urethra, adjacent to the bladder, works well at sealing off the passing of urine from the bladder to the urethra when it has a generally round or circular cross-sectional configuration. Support of the proximal urethra elevates it above the pelvic floor and subjects it to increases in intra-abdominal pressure, thus allowing compression and maintenance of continence. However, when this passageway becomes distorted into an elliptical or oval cross-sectional configuration, the sphincter muscle can not close properly, therefore, the

tendency for involuntary urine loss increases. SI can be caused by damage to the proximal urethra through trauma, radiation, sacral spinal cord lesions, prior surgeries, estrogen deficiency, or a congenital weakness. Neuromuscular damage from pregnancy, childbirth, and pelvic surgery is a common cause of SI. SI may also occur in men who have undergone prostatectomy, since the procedure may damage the proximal urethra.

The most common type of urge incontinence (UI) in elderly individuals is detrusor instability (DI) or "urge" incontinence. DI is urinary leakage due to spontaneous and uninhibited detrusor contractions occurring before the bladder is completely full.

Accompanying these contractions is an extremely strong need to urinate (urgency) and in some case complaints of frequency or nocturia. Another term often used is overactive bladder, which includes a cluster of symptoms; urgency, frequency, nocturia and in some cases DI. Most of the time the cause of DI is idiopathic, unless there is a presence of neurological dysfunction such as associated with stroke, cerebral tumors, Parkinson's diseases, multiple sclerosis, or Alzheimer's disease. However, a tumor, stone, foreign body, urinary tract infection or even prior surgical procedures to reduce incontinence can also cause this condition.

Overflow incontinence is the involuntary loss of urine associated with an over-distended bladder. This condition results in frequent to constant dribbling of urine in the absence of detrusor contractions. Symptoms may resemble those seen in SI or DI. In men, overflow incontinence may be due to an outlet obstruction, hypocontracted detrusor muscle, or a neurological disorder such as a spinal cord injury or multiple sclerosis. Although rarely seen in women, overflow incontinence is most commonly due to prior genitourinary surgery or pelvic organ prolapse. Individuals with overflow incontinence will typically retain large amounts of urine within the bladder after voiding. In this case, the ability to store urine is intact but bladder emptying is impaired.

Although urinary incontinence affects individuals of all ages, the majority of people are elderly and women. Among non-institutionalized people over 60 years of aged, the prevalence of UI ranges from 15 to 35 percent with women having twice the prevalence of men. Among institutionalized people, this number jumps significantly, as it is often the primary reason why individuals move to institutions. Urinary incontinence is also prevalent in the younger population affecting 10 to 30 percent of women and 1.5 to 5 percent of men.

Unfortunately, the social stigma and embarrassment associated with urinary incontinence contribute greatly to the distress, depression, isolation, and social withdrawal experienced by some affected individuals. Local complications such as skin breakdown, leading to bedsores and infection can also occur. In addition to the social and physical complications, the financial costs are enormous. UI is the second-leading cause of nursing home admissions and accounts for a large percentage of these health care costs. The annual costs of caring for both ambulatory and institutionalized persons with incontinence, including indirect costs (e.g. the treatment of injuries resulting from falls and complications such as skin breakdown), is estimated at several billion dollars.

Accordingly, there is a need for improved ways for individuals to manage their incontinence without embarrassment and with dignity and discreteness so that they may continue to lead active lives and enjoy a high quality of life. Specifically, because there are many mechanisms to maintain continence, involving the bladder, urethra, spinal cord and brain, it follows that a single tactic is often not enough to eliminate the possibility of involuntarily urine loss and soiling of one's clothing. Since no one single drug, device, or absorbent article can completely assure an individual of the impossibility of the embarrassment of an incontinent episode, a need exists to use anti-incontinence agents and absorbent articles in combination. A further need exists to provide the convenience of an incontinence prevention system to reduce the frequency of incontinent episodes and to protect a users' clothing from urine that is lost in one package. A combination of an anti-incontinence agent and an absorbent article provides individuals with a discreet, convenient and sanitary approach to manage their incontinence without the need for institutionalization or undue involvement by a medical professional.

SUMMARY OF THE INVENTION

Briefly, this invention relates to a combination for managing the involuntary loss of bladder control along with a method of using and manufacturing the combination. The combination includes an anti-incontinent agent capable of reducing urinary loss and an absorbent article capable of absorbing urine that is lost from the body. The anti-incontinent agent is enclosed in a first wrapper and the absorbent article is positioned adjacent to the wrapped anti-incontinent agent. A pouch encloses the wrapped anti-incontinent agent and the absorbent article to keep both items sanitary. A combination of a disposable absorbent article and information related to an anti-incontinent agent is also disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a front view of a pouch containing the combination.

Figure 2 is a cross-sectional view of the pouch shown in Figure 1 taken along the line 2--2 showing the combination as a wrapped anti-incontinent agent and an absorbent article.

Figure 3 is a cross-sectional view of the pouch shown in Figure 1 taken along the line 3--3 showing an alternative combination where the anti-incontinent agent *and* the absorbent article are wrapped.

Figure 4 is a plan view of a package containing a plurality of combinations.

Figure 5 is a cross-sectional view of a pouch shown in Figure 1 taken along the line 2-2 showing another alternative combination as a wrapped vaginal incontinence insert and a wrapped absorbent article.

Figure 6 is a cross-sectional view of still another combination of a drug that is blister packed to the wrapped absorbent article.

Figure 7 is a plan view of a pouch showing an opening tab.

Figure 8 is a plan view of a package containing a plurality of absorbent articles and written information.

Figure 9 depicts an example of written information.

Figure 10 is a flow diagram of a method of manufacturing a combination for managing the involuntary loss of bladder control.

Figure 11 is a flow diagram of a method for using a combination for managing the involuntary loss of bladder control.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIGS. 1-3, and 5, a combination **10** is depicted which includes an anti-incontinence agent **12** which is enclosed in a first wrapper **14** and an absorbent article **16**. The absorbent article **16** is located adjacent to the wrapped anti-incontinence agent **12** and may be enclosed in a second wrapper **42**, as specifically shown in FIG. 3. Both the anti-incontinence agent **12** and the absorbent article **16** are then enclosed in a pouch **18**, see FIG. 1, to keep them in a sanitary and discrete condition. The pouch **18** is formed from a single sheet of material, which has a first end **34** and a second end **36**. The first end can be positioned over the second end **36** in an overlapping relationship. Aligned perpendicularly to the first and second ends **34** and **36**, respectively, is a first side edge **38** and a second side edge **40**, that can be closed and sealed by ultrasonic sealing, heat sealing, adhesive or embossing. The first wrapper **14** and the pouch **18** can be formed

from a non-woven material such as a polyolefin, particularly polypropylene or polyethylene. Laminates or co-extruded films including of the mention materials are desirable as well. A desirable thickness is in the range from about .005 mm to .100 mm.

The anti-incontinence agents **12** can include both medicinal drugs and devices. While devices or surgery are the preferred means for treating stress incontinence, there are many drugs currently developed to treat urge incontinence which mainly focus on the parasympathetic activity of bladder contractions. Drugs with anticholinergic properties are the most common to be used to treat the unstable bladder. A number of other preparations have been used as well. Among these are antispasmodics, tricyclic antidepressants, calcium channel blockers, prostaglandin synthetase inhibitors, and other agents having an effect on smooth muscle contractility, such as potassium channel modulators. Agents typically used include oxybutynin, propantheline, imipramine, terodiline, dicyclomine, and flurbiprofen. These drugs are usually administered orally while some can also be administered as a transdermal patch or as a vaginal or rectal suppository. Drugs that are inhaled or injected are also considered. One such drug is Detrol® available from Pharmacia and Upjohn AB, Sweden. These drugs are associated with a number of side effects, however, which limit their usefulness and create the need for additional incontinence protection in form of an absorbent article or a device and an absorbent article. As a further advantage, drugs could be packaged with absorbent articles to last a pre-determined time period. For instance, in a ratio of two drugs, in the form of pills to last 12 hours each, and three absorbent articles, to last 8 hours each, to meet a daily need in the management of incontinence.

Devices focus on providing support to the bladder through the vaginal wall or preventing leakage of urine through the urethra. Due to pelvic floor weakness, organs prolapse and incontinence may result. Devices that correct this situation by supporting the bladder neck are known as pessaries or vaginal incontinence inserts. Women who leak urine during exercise and other physical activities may benefit from pelvic support from a pessary or vaginal incontinence insert. Urinary control inserts are inserted in the urethra to prevent leakage. The device resides in the urethra and bladder neck. They are available for women who have slight urinary incontinence episodes. The device is inserted using an applicator and is left in until the women needs to void. After removal, the device is discarded. One example of a device is taught is U.S. Pat. No. 6,090,038 which issued to Zunker et al. on December 21, 1998 this patent is entitled, "An Expandable Dome-Shaped Urinary Incontinence Device," also known as a vaginal incontinence insert. This patent is incorporated by reference and made a part hereof. A vaginal incontinence insert **48** is depicted in FIG. 5.

Absorbent articles **16** are designed to absorb body fluids, including urine or menses, and may come in different functional designs. Panty liners or shields are thin products, externally worn about the pudendal area and are designed primarily for very light urine loss. Intra-labial inserts are thin products internally worn inside the labia and are designed for very light urine loss. Sanitary pads or napkins are thin products externally worn about the pudendal area and are designed for light urine loss. Undergarments and protective underwear or refastenable protective underwear are designed for medium to heavy urine loss. Briefs are designed for heavy urine loss. In a final category of absorbent articles, absorbent inserts are used to supplement the absorbency of many of the previously listed absorbent articles. One example of an absorbent article is a POISE® Pad available from Kimberly-Clark Corporation having an office located at 501 North Lake Street, Neenah, Wisconsin 54956.

Referring to FIGS. 2 and 3, the absorbent article **16** may have a liquid pervious top sheet **26** a liquid impervious back sheet **28** and an absorbent core **30** disposed therebetween. The absorbent article **16** may also contain a peel strip **29**. The absorbent core **30** may also contain super absorbent polymer **32**. Superabsorbent is a material that is capable of absorbing at least 10 grams of aqueous liquid (e.g. distilled water) per gram of absorbent material while immersed in the liquid for 4 hours and which holds substantially all of the absorbed aqueous liquid while under a compression force of up to about 1.5 psi. Suitable super absorbent polymer is DOW 2035 available from the DOW chemical Company of Midland, MI. The liquid pervious topsheet **26** is designed to contact the body of the wearer and can be constructed of a woven or non-woven material, which is easily penetrated by body fluid. The liquid pervious topsheet **26** can also be formed from either natural or synthetic fibers. Suitable materials include bonded-carded webs of polyester, polypropylene and polyethylene, linear low-density polyethylene. Finely perforated film webs and net materials also work well. A desirable material is a composite of an apertured thermoplastic film positioned above a non-woven fabric material. Such a composite material can be formed by extrusion of a polymer onto a web of spunbond material to form an integral sheet. One example of this material is an apertured, thermoplastic polyethylene film bonded to a spunbond material. Spunbond is also a desirable topsheet. Spunbond material is a non-woven material, which is manufactured and commercially sold by Kimberly-Clark Corporation having an office located at 501 North Lake Street, Neenah, Wisconsin 54956.

The liquid impervious back sheet **28** is designed block the passage of body fluid.

The liquid impervious backsheet **28** can be made from any material having these

properties. A good material from which the liquid impervious backsheet **28** can be constructed is a micro-embossed, polymeric film, such as polyethylene or polypropylene. Bi-component films can also be used. A desirable material is polyethylene film with a thickness in the range from about .005 mm to .100 mm. Suitably, the liquid impervious backsheet **28** may have a pore size to permit the passage of air out of the article for comfort.

In some embodiments, a peel strip **29** is placed on one side of the absorbent article **16** and is designed to be removed by the user prior to the inner crotch portion of his or her undergarment. The peel strip **29** can be a white Kraft paper which can be coated with a silicone such as a silicone polymer commercially available from Akrosil having an office located at 206 Garfield Avenue, Menasha, WI 54952.

The absorbent core **30** can be any absorbent member, which may be compressible, conformable, non-irritating to the wearer's skin, and capable of absorbing and retaining liquid such as urine and other certain body exudates. The absorbent core **30** may be manufactured in a wide variety of sizes and shapes, including but not limited to rectangular, hourglass, "T"-shaped, or asymmetric. The absorbent core **30** may be manufactured from a wide variety of liquid-absorbent materials commonly used in disposable diapers and other absorbent articles. One such material is comminuted wood pulp, which is generally referred to as airfelt. Examples of other suitable absorbent materials include again without limitation, creped cellulose wadding; meltblown polymers including coform, chemically stiffened, modified or cross-linked cellulosic fibers; tissue including tissue wraps and tissue laminates, absorbent foams, absorbent sponges superabsorbent polymers, absorbent gelling materials, or any equivalent material or combination of materials.

Referring now to FIG. 4 a plurality of combinations **10** can be stacked and placed into a package **46**. The package **46** generally has the shape of a rectangle in its cross direction and represents a filled bag containing the containing compressed combinations **10**. The package **46** can be made of paper, or any recyclable or biodegradable material and laminate structures comprised of two or more of the aforementioned materials. In addition the package **46** may also be made of non-biodegradable or non-recyclable materials, such as a polymeric film.

Referring now to FIG. 6, the combination **10** includes an anti-incontinence agent **12** in the form of a drug **20**, which is enclosed in a blister pack **44**. The blister pack **44** can attached to the outside surface of the pouch **18**. A film, foil or non-woven material such as a polyolefin, particularly polypropylene or polyethylene or any such material

sufficient to maintain a drug's efficacy can form the blister pack **44**.

Referring now to FIG. 7, the combination liquid pervious top sheet **26** a liquid impervious back sheet **28** of the absorbent article **16** may be enclosed in a pouch **18** that may also contain an opening mechanism. In this case, an opening tab **50** is attached to the second end **36** between the first side edge **38** and the second side edge **40**. It is desirable that the opening tab **50** contains a hole in its center to provide an ergonomic means for grasping and pulling the pouch **18** open. The opening tab **50** can be made from a lightweight plastic, such as polyolefin, particularly polypropylene or polyethylene.

Referring now to FIGS. 8-9, the package **46** can contain written information such as a coupon **52** for a specific drug. For example, the coupon **52** can describe the drug DETROL® as specifically shown in FIG.9. Written information may also educate the consumer about urinary incontinence and the methods of treating urinary incontinence including but not limited to drugs and devices.

METHOD OF MANUFACTURING

Referring now to FIG. 10, a method of manufacturing the combination **10** will be explained with reference to the flow diagram. The method includes the steps of obtaining an anti-incontinent agent **12**, capable of reducing urinary loss. As described before, this could be a drug **20**, or a device **22**, or most desirably, a vaginal incontinence insert **48**. The anti-incontinence agent **12** is then enclosed in a first wrapper **14**. The first wrapper **14** is made of a thin sheet of material, such as a polyethylene, and is then cut to a desired length and placed on a continuously moving belt. The anti-incontinence agent **12**, is then placed on one half of the first wrapper **14**, and the second half of the first wrapper **14** is folded over the top of the anti-incontinence agent **12**, and may be sealed on the first and second ends **34** and **36**, and the first and second side edges **38** and **40**. Next an absorbent article **16** is positioned adjacent to the wrapped anti-incontinence agent **12**. The two items are placed on half of another thin sheet of material, such as polyethylene, and the second half of the material is folded over the items **12** and **16** and sealed on the first and second side edges **38** and **40** to enclose the combination **10** in a pouch **18**. The first and second side edges **38** and **40** can be sealed by ultrasonic sealing, heat sealing, adhesive, or embossing.

METHOD OF USING THE COMBINATION

Referring now to FIG. 11, a method for using the combination **10** will be explained with reference to the flow diagram. The method includes the steps of obtaining the

combination **10** for managing the involuntary loss of bladder control containing an anti-incontinence agent **12**, for example, a drug **20**, and an absorbent article **16**, for example, a sanitary napkin. The user opens the pouch **18** and then opens the first wrapper **14** around the drug **20** and takes the drug **20** and swallows it. Then the user takes the

5 absorbent article **16**, removes the peel strip **29**, and places it in his or her underwear. Alternatively, the user could use the absorbent article **16** first and then take the drug **20** last.

10 While the invention had been described in detail with respect to specific embodiments thereof, it will be appreciated that those skilled in the art upon attaining an understanding of the foregoing may readily conceive of alterations to, variations of and equivalents to these embodiments. Accordingly, the scope of the present invention should be assessed as that of the appended claims and any equivalents thereto.